

## **Board of Pharmacy**

### **Initial Statement of Reasons**

Subject Matter of Proposed Regulation:      Emergency Contraception

Sections Affected:      Amend 16 Cal.Code Reg. § 1746

Specific Purpose of the Proposed Changes:

The Board of Pharmacy (“board”) proposes to amend Section 1746 of Article 5 of Division 17 of Title 16 of the California Code of Regulations (“CCR”) for the purpose of revising the protocol utilized by pharmacists to furnish emergency contraception (EC) drug therapy pursuant to the standardized protocol developed and approved by both the Medical Board of California (MBC) and the California State Board of Pharmacy (Board). The MBC approved the proposed revisions to the EC protocol at its May 2011 Quarterly Board Meeting, and the Board approved the revised protocol at its October 2011 Board Meeting.

Existing law at Section 4052(a)(8) of the Business and Professions Code authorizes a pharmacist to furnish EC drug therapy as authorized by Section 4052.3 of the Business and Professions Code. Section 4052.3(a)(2) specifies that a pharmacist may furnish EC drug therapy in accordance with a standardized protocol developed and approved by both the MBC and the Board. Also, the development of the EC protocol by the Board must be made “in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The standardized protocol is specified at Title 16 Section 1746 CCR.

The protocol specified in this proposal was first adopted in 2004. Since that time, there have been changes in the availability of emergency contraception medicine and the manufacturers who produce the medication. It was also discovered that there is a typographical error in the board’s current regulation that requires correction (mcg instead of mg).

In 2011, the Board’s Executive Officer began working with a California Pharmacists Association representative (a women’s health specialist pharmacist) and two representatives of the American College of Obstetricians and Gynecologists to develop and finalize a protocol which would reflect the changes in medicine and manufacturing for EC. The resulting draft was considered and approved by the Medical Board of California at its July 2011 meeting. The Executive Officer provided updates to the Board’s Communication and Public Education Committee on January 10, 2011 and on September 26, 2011. In September 2011, the committee recommended that the Board initiate a rulemaking to repeal and to amend 16 CCR Section 1746 to be consistent with the proposed draft and update of the EC Protocol that was approved by the Medical Board in July 2011. This recommendation was adopted by the Board at its October 18, 2011 board meeting.

Existing regulation at 16 CCR § 1746(a) specifies that a pharmacist furnishing EC shall follow the protocol specified in subdivision (b) of the section.

This proposal updates a statutory reference specified in subdivision (a).

Existing regulation at 16 CCR § 1746(b) specifies the protocol to be used by pharmacists furnishing EC, to include authoritative references, purpose, information that must be communicated to the patient, training, documentation and other requirements. Paragraph (11) specifies a table of oral contraceptives used for EC; and paragraph (12) specifies a table of anti-nausea treatment options for use with EC.

Proposed amendments to Section 1746(b) would update statutory references within the section; would update the information that is to be communicated to the patient when the patient requests EC; would correct a typographical error; and would revise and recast the table of dedicated approved products for EC specified at paragraph (11).

#### Factual Basis/Rationale

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy and the administration of Chapter 9 of Division 2 of the Business and Professions Code.

Business and Professions Code section 4052 authorizes a pharmacist to perform specified procedures. Subdivision (a)(8) of this section permits a pharmacist to furnish emergency contraception drug therapy, as authorized by Section 4052.3.

Business and Professions Code Section 4052.3 specifies requirements and limitations related to a pharmacist furnishing emergency contraception drug therapy, and paragraph (2) of subdivision (a) specifies that a pharmacist may furnish EC drug therapy in accordance with a standardized procedure or protocol that is developed and approved by both the MBC and the Board.

#### Underlying Data

1. Relevant Meeting Materials and Minutes from the Board of Pharmacy, Board Meeting held October 18, 2011
2. Relevant Meeting Materials and Minutes from the Board of Pharmacy, Communication and Public Education Committee Meeting, September 26, 2011
3. Relevant Meeting Materials and Minutes from the Medical Board of California, Quarterly Board Meeting held July 28, 2011
4. Relevant Meeting Materials and Minutes from the Board of Pharmacy, Board Meeting held July 26, 2011
5. Relevant Meeting Materials and Minutes from the Board of Pharmacy, Board Meeting held May 3, 2011
6. Relevant Meeting Materials and Minutes from the Board of Pharmacy, Board Meeting held February 1, 2011
7. Relevant Meeting Materials and Minutes from the Board of Pharmacy, Communication and Public Education Committee Meeting, January 10, 2011

## 8. Economic Impact Analysis

### Business Impact

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the fact that the proposed regulation does not impose a new requirement on a pharmacy licensed with the Board of Pharmacy; rather, it proposes to modify the table of dedicated approved products used for emergency contraception and make other specified changes to the existing protocol, as jointly approved by the Medical Board and the Board of Pharmacy.

### Benefits

Business and Professions Code section 4005 states that “the board may adopt rules and regulations....pertaining to the practice of pharmacy....” Further, Business and Professions Code 4001.1 states that the “protection of the public shall be the highest priority for the Board in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.” The purpose of the proposed regulatory changes is to ensure that the drug products specified in the board’s emergency contraception drug therapy protocol specifies current drug information. Since the establishment of Section 1746 in 2004, there have been changes to drugs utilized for emergency contraception as well as the manufacturers that produce these drugs. Both pharmacists and patients will benefit from having an EC protocol available that has updated drug therapies.

### Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

### Consideration of Alternatives

The only alternative would be to not pursue this regulation. This alternative is not reasonable given that there have been changes in medications and the manufacturers who produce the medications. Updating the EC protocol specified in this proposal is necessary to provide pharmacists with a current list of medicines that are available for use in EC drug therapy.

No reasonable alternative to adopting or amending the regulations would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposed regulations.